

ECGWARE: AN ECG MARKUP LANGUAGE FOR AMBULATORY TELEMONITORING AND DECISION MAKING SUPPORT

Bernardo Gonçalves, José G. Pereira Filho

Computer Science Department, Federal University of Espírito Santo (UFES), Vitória, Brazil

Rodrigo V. Andreão

Electrical Engineering Department, Federal University of Espírito Santo (UFES), Vitória, Brazil

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Abstract: The ambulatory electrocardiogram (AECG) can be acquired and transmitted through mobile and wireless technologies and devices to foster heart's telemonitoring anytime, anywhere. This sort of service is purposeful when combined with ECG analysis systems and infrastructural support for providing context-aware services. Such setting makes efficient emergency services possible as well as improves the support to physician's decision making. This paper presents an ECG XML-based markup language that extends ECG reference standards in order to cover patient's heart telemonitoring during his/her daily activities. The ECG data format we propose is then applied in a real scenario.

1 INTRODUCTION

The rapid expansion of ICT has been allowing the creation of new services on Healthcare. The Telecardiology, in particular, has developed itself mainly through the transmission of the electrocardiogram (ECG). On one side, the ECG is fast, cheap and non-invasive when compared with other cardiology examination procedures. On the other side, the analysis of the ECG waveform can identify a wide range of heart illnesses, which are distinguished by specific modifications on ECG elementary waveforms. These are the reasons why ECG is the most frequently applied test for measuring heart activity in Cardiology. According to estimates, more than 100 million ECG's are recorded yearly in Western Europe (Fischer and Zywiets, 2003).

The storage and transmission of all these data have then been object of some initiatives concerning ECG format standardization. The oldest standards are AHA/MIT-BIH (Goldberger et al., 2000) and SCP-ECG (SCP, 2002), regarding records' storage and transmission respectively. In face of the Internet popularization, however, novel standards have been conceived in order to integrate interoperable and

user-driven solutions, standing out FDADF (Brown et al., 2002) and ecgML (Wang et al., 2003), both based on the XML markup language.

Nonetheless, such standards do not take into account heart's telemonitoring, which calls for the representation and transmission of the ambulatory electrocardiogram (AECG). The portable device that records the AECG was invented by Norman Holter in 1957. Since then, the ICT advances in addition to improvements in the accuracy of ECG software-based analysis systems have opened new potential uses to the AECG. Indeed, it is largely employed by the medical community, mostly for diagnosis and/or therapeutic treatment of the myocardial ischemia, which constitutes a pre-infarct. Since most ischemia episodes are related to increases in heart rate possibly associated to day-to-day variability of physical or emotional activities, AECG is indicated for patient's heart monitoring throughout his or her daily activities. With this in mind, the most suitable duration of a recording session to detect and quantify ischemia episodes is probably 48 hours. Some experiments point out that most patients are quite comfortable wearing the recorder for 48 hours (Crawford et al., 1999).

Besides, with the advent of a new Computing paradigm, the Pervasive Computing, context-aware

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systems provide new features, standing out for collaboration among professionals, systems, and action triggering from the detection of changes in the context of the user. This can be verified with the growth of initiatives dedicated to patient's monitoring, whether at home or in emergency situations wherever they take place. An example is the Awareness project (Awareness, 2007). Such efforts have taken advantage of the latest advances in mobile and wireless technologies and devices, in general, and may rely on signal processing algorithms, in particular, in order to provide both alarms generation and decision making support.

In face of all these aspects, we advocate that an ECG data format should cover the particular issues concerning telemonitoring through AECG, such as the ones related to emergency assistance (e.g. patient's location), or the activities performed by the patient during the ECG recording session (e.g. rest, physical exercise, routine activities, etc.). In this article we propose a novel ECG data format that extends former reference standards in order to cope with real-time telemonitoring and decision making.

The paper is organized as follows. Section 2 discusses the background of ECG data standards as well as aspects of telemonitoring; Section 3 presents the ECG data format we propose in this paper; Section 4 introduces a usage scenario where the format proposed is applied; and, finally, Section 5 concludes the paper and depicts future work.

2 BACKGROUND

Throughout the last thirty years, we can notice a regular evolution of standards regarding ECG record's representation and transmission. One may state that each standard resembles its purpose and the ICT environment at the time of its arising.

Since 1975, the Massachusetts Institute of Technology (MIT) together with laboratories of the Beth Israel Deaconess Medical Center have carried out research concerning medical examinations analysis and related points. As a result, in 1980 the MIT-BIH Arrhythmia Database was deployed after testing and standardization for arrhythmia detection and evaluation. Also at this time, the American Heart Association (AHA) has deployed the AHA Database for Evaluation of Ventricular Arrhythmia Detectors (Goldberger et al., 2000). Together, those databases have been largely used and played an important role on research in the field of Cardiology (Moody and Mark, 2001).

The AHA/MIT-BIH standard has focused on bringing in an ECG records' library for providing

input for developers of ECG analysis systems. It, in fact, is responsible for substantial advances on ECG data processing. This standard, however, does not aid interoperability over the Internet due to its tight coupling with programming language. Moreover, it is not human readable, which is a desirable requirement with respect to the analysis of electrocardiography's domain experts.

Later, there was a great effort to conceive the SCP-ECG - Standard Communications Protocol for Computer-Assisted Electrocardiography (SCP, 2002). SCP-ECG is a specification concerning ECG data format as well as transmission procedure from the acquisition device to the host where the message is stored and retrieved. From 1989 to 1990, it was carried out a survey on ECG compression methods that has as a result led to an original approach for signal compression (Fischer and Zywiets, 2003).

Nonetheless, despite the SCP-ECG allows suitable data compression, the elements of the format are defined at the bit level. This obstructs changes on the format, either for updating or customization, as well pushes final applications (i.e., ECG viewers) to be familiar with SCP codes. As per (Clunie, 2004), SCP implementation is an awkwardly task especially on the compression mode. Considering that computational resources are currently more accessible than at the creation of the SCP, bandwidth over the networks, memory capacity and disc space are not main concerns as they were before. Meanwhile, other concerns have taken place on Telemedicine scenarios, such as the need for platform- and application-independent solutions involving human readable data models.

In this trend, and also as a result of the grown popularity of the Internet, XML-based formats as FDADF and ecgML have been increasingly used on Telecardiology research. The Extensible Markup Language (XML) has played an important role on data exchange over the web, especially by providing the separation of data content and presentation. After XML has become a W3C recommendation in 1998, several domain specific languages were created from a XML Schema. In this way, several committees of Health organizations such as CEN/TC251, Health Level Seven (HL7), American Society for Testing and Materials (ASTM), etc, have worked on the development of recommendations for using XML on Telemedicine research.

The Food and Drug Administration (FDA) has carried out a survey on ECG standards and has chosen the XML technology for data representation based on the HL7 ECG annotation message v3 (HL7, 2003). As a result, in 2002 it has produced the FDA XML Data Format (FDADF). The FDADF is

an effort to reach the standardization of ECG data representation for all stakeholders share the same view (Brown et al., 2002). Looking for addressing requirements previously defined, the scope of the FDADF specification covers ECG data as much as significant submission information. FDADF has achieved a significant progress on ECG data representation by using XML. Nevertheless, as per (Wang et al., 2003), it does not exploit as far as possible XML features. That is because, on account of ECG viewer applications' concerns, it has incorporated elements related to data presentation in its metamodel, rather than to cope only with data content.

More recently, in 2003, the *ecgML* was developed in face of the increased demand for a standardized application- and platform-independent ECG format. This one has been conceived from the former standards (especially the FDADF), reusing then concepts and nomenclature. The *ecgML* allows ECG data analysis and transmission between heterogeneous platforms (Wang et al., 2003). Indeed, rather than FDADF, the *ecgML* has comprised only data content. It holds benefits such as flexibility, readability and descriptiveness. Nonetheless, as remarked by the authors themselves, there are issues left to evaluation, such as concepts still not covered in *ecgML* (Wang et al., 2003).

As a matter of fact, the more is the emergence of new technologies increasing the usage potential of computer systems, the more there are usage scenarios foreseen. As a result, further information can be explored promoting then more useful services. In this way, a data format for wrapping biomedical signals, in fact, constitute an interface between data acquisition and data usage systems (see Figure 1). Therefore, such a data format should not be a restrictive mean for useful data acquired from sophisticated devices. As opposed, it should abstract the complexity related to biomedical signals acquisition to the health professionals' environment. This concern is particularly worth in context-aware telemonitoring of patients' heart relying on both wireless and mobile technologies and devices and the transmission of AECG. The existing ECG standards, however, lack this concern and neither were conceived from advanced modeling techniques such as domain ontologies.

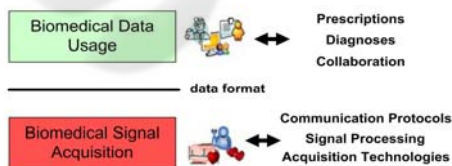


Figure 1: Separation between data acquisition and usage.

As an effort to cover this gap in literature, we have carried out an extensive research on the Electrocardiography domain. At this time, we have developed an ECG domain ontology which is presented elsewhere (Gonçalves et al., 2007), and the *ecgAware*, a XML-based ECG data format which is the focus of this article. The *ecgAware* extends former standards especially by covering AECG aspects related to context-aware telemonitoring. On the next section we elaborate on the *ecgAware* markup language, remarking the main issues we have previously mentioned.

3 ECGAWARE

The *ecgAware* has a tree hierarchical structure which is described in the following in a prefix way, i.e., expanding each significant XML complex element on the left. The main elements are depicted on diagrams in the figures 2 to 5. XML elements and attributes are both referenced in bold and italic, (the elements have the first letter capitalized); optional elements or attributes are dotted in the diagrams.

The *ecgAware* model constitutes an *ECGStudy* (see Figure 2) of a single patient, which integrates attributes that provide some prior data. These data are *studyID*, a unique ID; *studyTimeStamp*, i.e., date and start time of the latest ECG record present in the message; *dateTimeZone*, which supplies the acquisition local time zone (based on SCP); *studyLocation*, holding the latest location obtained; the *alarm* attribute indicates that at least one record inside the study contains an abnormal event, which may be either detected by an ECG analysis system or triggered by the patient. In case it is flagged true, the *ecgAware* message supports an efficient emergency service by the *studyTimeStamp* and *studyLocation* attributes. Finally, *computerID* identifies the machine where signal processing takes place (based on SCP) and *investigatorID* is a unique ID of the health professional which blames for the ECG study (based on FDADF). *ECGStudy* has three child elements: (i) *PatientData*, for patient's demographics data and electronic record; (ii) *Record*, the ECG record produced in each recording session; and (iii) *Comments*, for free text.

The *Demographics* element then comprises data for identifying and contacting the patient (inspired on *ecgML*); its child elements are *Name*, *Sex*, *DOB* (date of birthday), *Address*, *Phone*, *Fax* and *Email*. Meanwhile, *EPR* represents a basic patient's electronic record; it is composed by patient's *Height* and *Weight*; the boolean elements *Hypertension*, *Diabetes*, *Smoker* and *Alcohol*; *Other* for inserting

other clinical data; and *Comments*, a free text field. *Demographics* and *EPR* may be obtained by means of a simple anamnesis. Those data are optional because there may be situations (e.g. an emergency) where there is no time for collecting them.

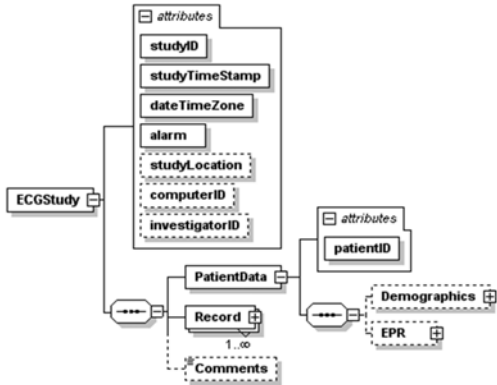


Figure 2: The *ECGStudy* root element.

ECG data are laid in the *Record* element (see Figure 3). A *recordID* attribute identifies the record; The *RecordingDevice* element describes the acquisition device used to obtain the record (based on FDADF) and filtering technique(s) performed by it (based on SCP); *RecordingSession* bears the recording session context, and is especially useful for emergency services and decision support; *RecordChannel* (min. one, max. twelve) constitutes the ECG signal acquired through a channel; *GlobalAnnotations* and *GlobalMeasurement* in turn (inspired on FDADF and SCP respectively) are annotations and measurements related to all leads; and lastly, *Report* is a record finding carried out either by a physician that interacts with a system or by an analysis system to be further verified by a confirming physician.

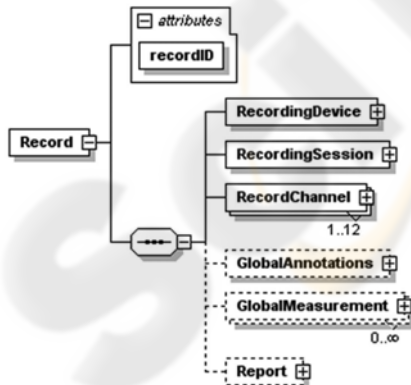


Figure 3: The *Record* element.

RecordingDevice has a *deviceID* to identify the device by a serial number. It has also a *Type*, a

Manufacturer and a *Model* (e.g. Holter, Space Labs, 90205). The *BaselineFilter*, *LowpassFilter* and zero or many *OtherFilter* elements constitute noise filtering to overlook signal frequency components over superior bounds and other filtering possibly performed on the signal, respectively.

As we previously mentioned, patient's heart continuous telemonitoring can support diagnosis and/or therapeutic treatment of the myocardial ischemia. This is possible by means of a long-term AECG *RecordingSession* (see Figure 4). With this in mind, we included the *Activity* element, which lays up a description of each activity performed by the patient during the recording session (e.g. rest, physical effort, etc). This information can be either obtained by user interaction with the ECG acquisition system (in replacement of the paper in which patients used to populate his/her activity/time over the recording session); or much better, acquired by a sensor device such as a video camera jointly with an eye-tracking system (Zhai, 2003), or by other sensing techniques (Boudy et al 2006).

Still from a context-awareness standpoint, the patient's context during a recording session may be used, for example, to guide an ambulance to the patient's location whenever an emergency takes place. This sort of feature is possible thereby small mobile devices which permit, nowadays, patient's vital signs and location telemonitoring even in outdoor scenarios. That is why we included the *AcquisitionLocation* element, which holds the latest patient's location acquired in a *RecordingSession* from a device such as GPS.

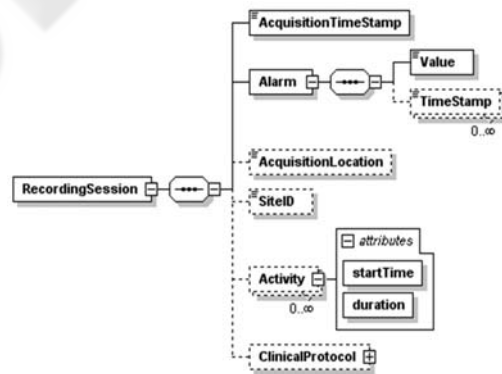


Figure 4: The *RecordingSession* element.

Besides, *AcquisitionTimeStamp* hands over date and start time of each session; *Alarm* flags on a true or false *Value* for abnormal event(s) either identified by an ECG real-time analysis system or triggered by the patient, and keeps on zero or many *TimeStamp* elements date and time of the detected event(s). In case *Alarm* is true, on one side, an *ecgAware*

message comprising a partial record must be transmitted as far as the abnormal event was detected; on the other side, the whole ECG must be recorded including all alarm events occurred during the recording session related to it. Lastly, *SiteID* is an abstract description of the place whereby the session took place (e.g. domicile).

ClinicalProtocol, rather than in other ECG data formats, is placed in the *RecordingSession* element. Indeed, it is related to the meantime of a session instead of a range of sessions. It then is composed by *DiastolicBP* and *SystolicBP*, taken in the session at some *timestamp* under a value *unit*; *Medication*, specifying drugs which the patient has been using; and finally, *Sweaty* and *Pale* (based on ecgML) indicating true or false for abnormal sweat and abnormal looking skin on the face, respectively.

The ECG signal is obtained from correlated observation series taken at the same time by electrodes placed on some positions on the human body. These placements, when combined, provide different viewpoints of the heart electrical activity, i.e., the ECG leads. In Electrocardiography twelve leads were standardized. ECG data is thus laid up on one or more (max. twelve) *RecordChannel* elements (see Figure 5) standing for the leads. The *Channel* element identifies the lead (e.g. Lead II); *Waveform* contains the XY signal; *ChannelAnnotations* and zero or many *Measurement* elements, in turn, are annotations and measurements related to a lead (all inspired on FDADF and ecgML).

The ECG samples are obtained from the observations performed by the device over the time, and thus constitute XY values. They are situated in the *Waveform* element by *XValues* and *YValues*. However, since observations are evenly spaced in time, we do not need to store time values (*XValues*) in the XML document. They rather can be easily obtained by the *Xoffset*, *Duration* (of the record) and *SampleRate* elements (all of them holding a *unit* attribute). The sample values (*YValues*), otherwise, must be covered in the XML Document, even though there are different options to get it done. Those values have also a *unit* and may be laid up either (i) in an external file, which the link path is indicated by *FileLink*; or (ii) by an integer series *IntValue* (which can be easily converted to float by using a scale); or even (iii) by a binary encoding (*BinaryData*). Both *IntValue* and *BinaryData* are composed by the *From*, *To*, *Data* and *Scale* elements. They are respectively the beginning and ending of the waveform in the X axis, the sample values, and a scale factor to obtain the real number of each value. The *BinaryData* has also a data *encoding* attribute (e.g. Base64).

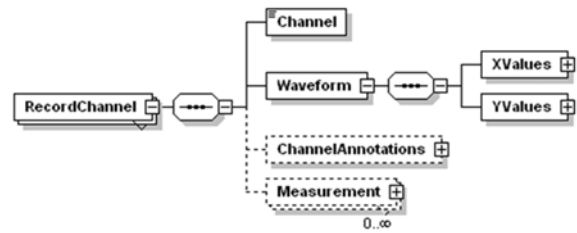


Figure 5: The *RecordChannel* element.

ChannelAnnotations mark significant events identified on the waveform. They are carried out by an *author*, which may be either a system or a physician. Annotations may be either about points (*PointNotation*) or time intervals (*WaveNotation*). The former involves a *PointLabel* describing the point, an *XValue*, an *YValue*, and a *Comment*. The latter in turn marks beginning, peak and ending time values of one or more waves by the *Onset*, *Peak* and *Offset* elements, respectively. Moreover, it holds also an *Interpretation* (e.g. abnormal) of the waveform in this time interval. It is worth to say the *WaveNotation* element is basically addressed by the elementary forms, or waves, which compose the heart beat. They were defined by Einthoven in 1895 as PQRST; we can abstract the elementary forms by *Pwave*, *QRScomplex* and *Twave*. Zero or many *OtherWave* elements may also be considered. On different leads, a specific elementary form can be viewed in a better or worse way, exception by the QRS complex, which can be well viewed through whichever lead. This is the reason why we made only the *QRScomplex* element required on *WaveNotation*.

Besides annotations, zero or many *Measurement(s)* can be made either of the duration or of the amplitude of elementary forms. We can distinguish that by means of the *label* and *unit* attributes, e.g. P-duration and ms (based on ecgML and SCP).

Global annotations and measurements, as opposed to the channel ones, are related to all leads. This sort of annotations then can be performed either by a physician marking a vertical line correlating the same *XValue* on all leads through an ECG viewer application, or simply by a system from an average of the correlated channel annotations. The *GlobalAnnotations* element (inspired on FDADF) thus discriminates itself from *ChannelAnnotations* only by, on the former, all elementary forms are required. The *GlobalMeasurement* element (inspired on SCP), otherwise, has exactly the same structure of the channel *Measurement*. The former, however, is obtained from an average of the correlated channel measurements.

Finally, we have admitted a **Report** element to provide a finding about the ECG record. This report is carried out by an **author** which may be either a system or a physician that has saw the record through an application and then has edited it. The finding comprises **HeartRate**, **ElectricalAxis** of the heart, and **Diagnosis**.

4 USAGE SCENARIO

As part of a research program in healthcare and bioengineering technologies at UFES, in Brazil, we have been developed in the TeleCardio project a context-aware system for remote monitoring patients with cardiological syndromes (Andreão et al., 2006a). In TeleCardio, the patient can have his/her heart activity monitored anytime either in domicile, ambulance, or outdoor scenarios. The TeleCardio system carries out the transmission of the AECG in combination with contextual data (e.g. location) in order to allow physicians follow their patients' condition in real-time and report diseases remotely. TeleCardio, in fact, is a rich field for applying *ecgAware* to wrap and deliver ECG signals, related data and contextual data. The Figure 6 depicts the TeleCardio architecture.

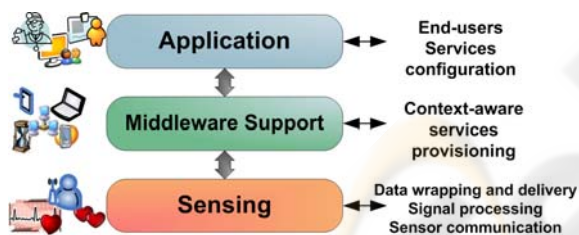


Figure 6: TeleCardio Architecture.

The Sensing layer comprises the *ECG Wrapper*, an integrated system (hardware and software) for acquiring the ECG signal from a Holter device. This system handles wireless communication with the device, signal processing, data wrapping and delivery. One of the components of such system is an ECG analysis software (Andreão et al., 2006b), which makes use of an enhanced approach for ECG classification and segmentation. This software thus produces the ECG enhanced data for populating the *ecgAware* model. The ECG Wrapper, in fact, hides all complexity related to biomedical signals acquisition for the middleware and application layers by delivering *ecgAware* data to them.

The middleware layer, named Infraware (Filho et al., 2006), provides context-aware services for supporting client applications. Examples of such

services are: (i) to supply subscription management for the health client applications as well as to manage the interactions between these applications and the ECG Wrapper; (ii) to guarantee privacy and access control to patients, physicians, etc; (iii) to guide an ambulance from the patient's domicile to a hospital by choosing the best traffic routes; and (iv) interpretation of pieces of information in order to trigger emergency services, e.g. when **alarm** is flagged true.

The Application layer in turn addresses services configuration, users' profile and so on. The Figure 7 shows a web application that we have developed in the TeleCardio project whereby physicians can view the patients' ECG signals and take advantage of the *ecgAware* features. By means of such an application, the physician can follow his/her patient's heart activity anywhere, anytime. In case an emergency takes place, the physician is notified both by the application (in case he/she is online on the system) and by a SMS message his/her cellular phone.

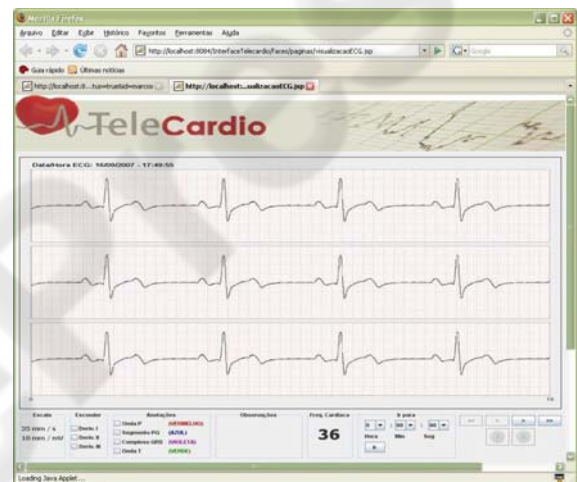


Figure 7: Snapshot of the TeleCardio's ECG viewer.

Because we are speaking of telemonitoring in real-time, the ECG Wrapper has then to pack the AECG record into small pieces of *ecgAware* data for delivery by each 30 seconds. This time interval is related to hardware optimal operation as well as the emergency procedure. In fact, one could argue that the XML format do not meet computational efficiency as much as a binary format. Nonetheless, we can overcome this either by using a binary file to store and transmit the ECG XY data (see the **FileLink** element) or by developing a compression procedure in order to reduce the XML file. In (Erfianto, 2004), for example, the compression scheme has reached a reduction of up to 53% for ECG data and 87,5% for patient data. The technique

used parses the XML document to an ASN.1 format and, in the sequel, to a binary-encoded format.

5 FINAL CONSIDERATIONS

Currently we have advanced wireless and mobile technologies and devices as well as systems that carry out biomedical signal's analysis through signal processing algorithms. In this work we have argued on the worth of taking advantage of such resources in order to improve emergency services and decision making support in the Healthcare domain. In this way we can make the acquired sensor data much more useful.

In the scope of Telecardiology, in particular, we have elaborated in this paper how the existing ECG data format standards lack this concern. We have then proposed a novel ECG model striving not only for application- and platform-independence and focusing data content, but also admitting elements to address telemonitoring concerns. As a result, we can provide better emergency services and decision making support, meeting then the requirements related to pervasive scenarios in Healthcare.

The first usage results remarks *ecgAware* is suitable for its purpose. After all, throughout the TeleCardio evaluation we will test such data format under an intensive usage by one or more medical communities. Hence, we will have statistical metrics to better evaluate it.

Former usage scenarios in Telemedicine, e.g. remote reporting, are still covered by the *ecgAware* data format. In fact, it embraces features of the former ECG reference standards. Future usage scenarios may cover other vital signs telemonitoring. This is feasible by using the same research methodology, i.e. exploring each biomedical signal domain as we did in this work with the ECG. Moreover, the XML technology provides flexibility such that we can incorporate several XML schemas to a root one. We thus can keep the elements regarding telemonitoring, in general, and to design a record structure for each biomedical signal we choose to bear.

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